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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,707	09/30/2004	Jeffrey Lee Spray	B0368-US01	5706
24994	7590	03/24/2010		
CaridianBCT, Inc. Mail Stop: 810 1F2 10811 WEST COLLINS AVE LAKEWOOD, CO 80215			EXAMINER DANEGA, RENEE A	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 03/24/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/711,707	Applicant(s) SPRAY ET AL.	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-9 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 25 is objected to because of the following informalities: Claim 25 appears to be amended but is not designated in the parentheses preceding the claim. As such, examiner is examining the claim as amended. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwaan (US 4532969) in view of Lynn (US 5167656).

- Regarding claim 1, Kwaan teaches a biologic fluid sampling device comprising a biologically compatible reservoir having an interior chamber (15) for receiving a biologic fluid, a fluid egress port (16), and a fluid a needle (12) in fluid communication with said chamber through said fluid egress port (16), and a valve (3) interposed between said chamber and said needle whereby flow of biologic fluid from said chamber through said needle may be selectively controlled and a rigid base (10) supporting said valve (3) said base (10) being directly and rigidly coupled to said reservoir (16) and to said needle (12) and supporting said needle in fixed

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relationship with respect to said reservoir (Figures 5A-B, 6). Kwaan doesn't expressly teach a fluid access port on the reservoir. However, Lynn teaches a fluid sampling device in which additional fluid reservoirs (22) (24) are attached to the primary reservoir (12) via a fluid access port (20) (Figure 1). It would have been obvious to one of ordinary skill in view Lynn to provide an inlet port in the reservoir of Kwaan in order to add or remove fluid from the reservoir.

- Regarding claim 3, Kwaan teaches the rigid base has at least one sidewall (2) coupled to said base (1) (Figure 1).

4. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwaan modified by Lynn as applied to claim 1 above, and further in view of Danby et al (US 4725269).

- Regarding claim 4, Kwaan modified by Lynn teaches any known valve component can be used (column 25-28, Lynn) but doesn't expressly teach the valve to be a crimp valve. However, Danby teaches a crimp valve assembly having a rigid base (4) and sidewall (2) supporting the valve and coupled to a reservoir area (interior of the device) with a central beam (216) extending generally linearly from the fluid egress port and capable of being coupled to a needle (212) and supporting it in a fixed relationship relative the reservoir (Figures 1 and 15) which uses a pinch valve for precise manual flow control (column 1, lines 10-15). It would have been

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obvious in view of Danby to provide a pinch valve clamping device in Kwaan modified by Lynn in order to provide precise manual flow control.

- Regarding claim 5, Danby's device has a flexible tube (208) extending along the central beam from said fluid egress port wherein said valve comprises an arm (28) pivotally (6) connected to said rigid connector and extending across the tube and central beam (when closed) such that said tube can be compressed (60) between said beam and said arm by movement of said arm (Figures 2, 6).
- Regarding claims 6-7, Danby's arm has a fixed end (at hinge 6) and a moveable end (at 24) and said device further comprises a bracket or opposing latches (20, 22) mounted on said connector (4), said moveable end of said arm (28) being connected to said bracket (when closed) and a hinge mounted on said connector (6) (Figures 2, 6).
- Regarding claim 8, Danby's device comprises a ridge extending along said arm (point 229) configured to selectively press (60) against said tube (Figure 2, 15).

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwaan modified by Lynn as applied to claim 1 above, and further in view of Coburn (US 4932418).

- Regarding claim 9, Kwaan modified by Lynn doesn't expressly teach a bottle adapter connected to the valve. However, Coburn teaches a bottle adapter (41) surrounding a needle (21) of a sampling device in order to fit

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the needle to a vial (35) or safely store the needle (55) (Figures 10-11). It would have been obvious in view of Coburn to provide a bottle adapter on the needle of Kwaan modified by Lynn to enable the needle to connect to vials securely or safely store the needle when not in use.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kwaan modified by Lynn as applied to claim 1 above, and further in view of Richmond (US 6068617).

- Regarding claim 25, Kwaan modified by Lynn teaches a fluid product bag (12) and a tube (28) connecting the bag (12) to the fluid access port of the reservoir (32) but doesn't expressly teach how the bag and tube are connected (Figure 1 Lynn). However, Richmond teaches a tube (51) connecting to a bag (38) with a frangible valve (54) interposed in the tube to permit selective fluid access to a receptacle (20) (Figures 1, 2A-B). It would have been obvious in view of Richmond to one of ordinary skill in the art to provide the connection means of Kwaan modified by Lynn to secure the tubing to the fluid product bag.

Response to Arguments

7. Applicant's arguments filed 1/5/10 have been fully considered but they are not persuasive. The Kwaan reference has been added to overcome the amendment of direct and rigid coupling in claim 1 as referenced above. Danby teaches a central beam or the central area that the tubing can follow extending along (8) - (12) with (28) forming a segment against which the tube can be compressed (Figure 2). With regards to claim

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5, the pressure plate is part of the arm which moves to cut off flow in the tube. With regards to claims 6-7, examiner thanks applicant for point out that (229) was the point being referred to.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736